DRUG UTILIZATION REVIEW BOARD		
Meeting Minutes, Open Session		
September 14, 2005		
DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas September 14, 2005	Members Present: Michael Burke, M.D., Ph.D, Chair; R. Kevin Bryant, M.D., CMD; Dennis Grauer, Ph.D.; Kevin Kentfield, PharmD; Linda Kroeger, ARNP;Roger Unruh, D.O.; Tom Wilcox, R.Ph. SRS Staff Present: Anne Ferguson, R.Ph., DUR Program Director; Mary Obley, R.Ph.; Wanda Pohl EDS Staff Present: Karen Kluczykowski, R.Ph.; Deb Quintanilla,	Representatives: Jeff Knappen (Allergan) Robb Host (Cephalon) Jessica Hurtig (Gate), Barry Adams (Upjohn), Jerry Roth (Steere), Paul Fung (FirstGuard), Ron Rhodes, (UCB), Sandra Berriman, (Pfizer), Bradd Rupp (Topeka Urology), Ann Gustafson (GlaxcoSmithKline), Mike Moratz (Merck) Bruce Kirby (Genetech), Jim Goddard (Shire), Brad Smoot (Pfizer), John Kiefhaber (KPhA), Dr. James Warren (Cephalon)
TOPIC	R.N. DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 10:00 a.m.	
II. Announcements	No new announcements	
III. Review and Approval of July 13, 2005, Meeting Minutes	There were no additions or corrections to the July 13, 2005 meeting minutes.	A motion to approve the minutes as written was made by Dr. Kentfield and seconded by Dr. Unruh. The motion carried unanimously by role call.
IV. Old Business A. Growth Hormone 1. Discussion of Prior Authorization Criteria	Anne gave a brief history/update on issues surrounding growth hormone Prior authorization(PA) criteria. She presented a PA criteria draft based on recommendations submitted by Dr. Moore which would replace current criteria. The draft excludes conditions of Idiopathic Short Stature and Short for Gestational Age.	
2. Public Comment	 No public comment Dr. Burke states Dr. Moore and Dr. Dykstra requested less emphasis on lab values and more on growth data, is this reflected in the draft criteria. 	
	 Anne stated that this is addressed in the current draft. Dr. Moore's recommendations were accepted entirely for conditions that will be covered. 	
3. DUR Board Recommendations	 Dr. Unruh stated he believes recommendations are reasonable and appropriate. With no further board discussion, a motion was placed before the board. 	A motion was made by Dr. Unruh to adopt the growth hormone Prior Authorization (PA) criteria draft and seconded by Dr. Bryant. The Board would like to review the number of beneficiaries approved for growth hormone and the number of denials for the one year period post-implementation of the new criteria. The motion carried unanimously by role call.

ТОРІС	DISCUSSION	DECISION AND/OR ACTION
V. New Business A. Actiq® 1. Discussion of Prior Authorization Criteria 2. Public Comment 3. DUR Board Recommendation	 Anne presented utilization data for Actiq®, and reviewed package labeling for indications and dosing. Based on this information, a PA criteria draft for Actiq® was presented. Ms. Kroeger questioned if this medication is restricted currently. Anne stated that there are no restrictions in place currently. Dr. James Warren (Cephalon) presented information on breakthrough pain. Dr. Burke stated today's focus is on the formulation of the medication not the effectiveness of fentanyl in pain treatment. Dr. Burke read a statement submitted by Dr.Schewe. She is in favor of using Actiq® for cancer patients. She feels four units/day is a reasonable limit. If more than four units per day is needed, then the baseline analgesic meds may need to be adjusted. Dr. Burke would like to see #1 of criteria modified to readpain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. With no further board discussion, a motion was place before the board. 	A motion was made by Dr. Bryant to accept the PA criteria draft and seconded by Dr. Grauer with the modifications to #1 as stated by Dr. Burke. The motion carried unanimously by roll call.
B. Erectile Dysfunction Drugs Viagra®, Levitra®, Cialis®, Caverject®, Edex®, Muse® 1. Discusssion of Prior Authorization 2. Public Comment	 Anne reviewed the directive from Centers for Medicare and Medicaid Services (CMS) on the issue of coverage of erectile dysfunction drugs for registered sex offenders. It stated that the use of these drugs in sex offenders is not appropriate and Medicaid should not pay for them in this situation. Medicaid needs to implement appropriate controls to ensure this directive is met. Anne reviewed the proposal for prior authorization that was developed by State staff. Along with clinical criteria, the PA would require renewal on a monthly (calendar) basis and limit the quantity to 2 units/month or 1 two-unit kit per month. Dr. Burke questioned if ED drugs are on PDL currently. Anne stated no. Deb Q. stated injectables require PA, but oral ED drugs have a quantity limitation only. Dr. Brad Rupp (Urologist) gave testimony about his practice and feels the limit should be increased to six units/month. Discussion surrounded the issue of accepting phone calls for the PA approval process vs. paper form. Mary stated phone calls would be accepted between physician and PA unit. Dr. Grauer asked what number of phone calls do we anticipate. Deb Quintanilla stated based on a report ran January 	

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	 through July of this year, there are an average of 377 beneficiaries receiving the ED drugs. They anticipate receiving 750 calls a month. Deb Q. stated the process usually starts with the pharmacy, but would require a call to the physician to verify nitroglycerine history. Dr. Bryant questioned whether it would be possible to leave the PA approval in place for a year and review the registered sex offender list as it is updated; then deactivate PA's as necessary in an attempt to decrease phone calls to the PA unit. Nialson stated we will accept all recommendations from the Board for improving the process and will take them back to the appropriate level for review. Ms. Kroeger feels the restriction is going to prevent prescribing these drugs due to the burden of obtaining the PA. Dr. Burke stated one option would be to not cover the ED drugs. Mary stated this is a recommendation we will elevate to the proper level for review. Dr. Burke read Dr. Schewe's statement. She stated she views the proposed PA as restrictive, but approves of it as long as oral contraceptives are covered for female beneficiaries. Mary stated that Medicaid does cover oral contraceptives for females. 	
3. DUR Board Recommendation	 Dr. Burke recommends we accept criteria as is and review the activity and cost burden created by the new PA six months post implementation. With no further board discussion, a motion was placed before the board. 	A motion was place before the board by Dr. Kentfield to accept the PA criteria draft as prepared and seconded by Dr. Bryant. The motion carried unanimously by roll call.

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C. Provigil® 1. Review Update/Diagnosis Requirement 2. Public Comment	 Anne presented information on Provigil® including utilization data, current policy regarding coverage for specific diagnoses, and new FDA approved indications. Items for discussion were to remove generic diagnosis code of 780.54 (hypersomnia not elsewhere specified and revise current policy to accept new FDA approved indications in the form of ICD-9 codes as covered diagnoses. Mr. Host (Cephalon) presented information to the DUR Board regarding Provigil®. 	
3. DUR Board Recommendations	 Dr. Burke read Dr. Schewe's comments. She doesn't think shift work should be included, however, Dr. Burke pointed out it is an approved FDA indication. With no further discussion by the board, a motion was place before the board. 	A motion was made by Dr. Kentfield to update the policy by removing the diagnosis of 780.54 and add the new indications of obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder, ICD-9 codes
		780.57 and 307.45.and was seconded by Ms. Kroeger. The motion carried unanimously by roll call.
D. Amphetamine/ Amphetamine like drugs 1. Review/Update Diagnosis Requirement 2. Public Comment	 Anne presented utilization information on amphetamines and reviewed the current policy regarding diagnosis codes. Anne requested the Board determine if ICD-9 code 311 (depression) should be allowed as a covered diagnosis. Depression is not an FDA approved indication for this class of medication. Jim Goddard (Shire) stated that most States now have all drugs approved for Attention Deficit Hyperactivity Disorder (ADHD) in one policy requiring ICD-9 codes at point of sale including, Stattera® and Methylphenidate, and would like the board to consider such a change to the current policy. Mary stated she is not aware of the history surrounding the current policy and why some drugs were excluded, but this will be reviewed in the future. Dr. Burke stated that the issue before us today is to decide if depression is an acceptable diagnosis for use of amphetamines. Dr. Burke stated that in his review of the topic, this class of medication(amphetamines) has been used as augmentation therapy for depression; however, the actual data is limited and only supports use of methylphenidate. 	
3.DUR Board Recommendations	 Dr. Burke recommends a review of the current policies on amphetamine and amphetamine-like drugs at a later date and consider placing them all under one policy. With no further board discussion, a motion was placed before the board. 	A motion was made by Dr Bryant to remove diagnosis code 311(depression) and update required diagnosis codes to FDA approved indications for the current policy and was seconded by Dr. Unruh. The motion carried unanimously by roll call.

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E. Phentermine 1. Discussion of Current Prior Authorization Criteria 2. Public Comment	 Anne presented the current PA criteria for Phentermine pointing out that it is outdated and does not reflect current FDA approved indications. She is requesting the board to consider discontinuing the present PA criteria as mazindol is only available as an orphan drug and phentermine is only indicated for short term treatment of obesity. Options would be to non-cover phentermine or to cover phentermine for short term treatment of obesity. Dr. Bryant questioned how many requests the PA unit has taken for phentermine. Anne stated Deb Q. created a report that indicated 9 request over the last year for weight loss which were all denied due to not meeting criteria. Mr. Wilcox stated phentermine is available as a generic and would be a less costly agent as compared to Meridia® and Xenical®. The current weight loss PA criteria for Meridia® and Xenical® was distributed to the board members. Anne stated that there are some differences to consider. Mary pointed out most criteria is the same aside from age, and length of treatment. Dr. Burke stated that the package labeling specifies a few weeks treatment and there is not a black box warning associated with this drug. Dr. Kentfield questioned if there is an age requirement. Jessica Hurtig (Gates) informed the DUR Board that her company markets the brand name drug of phentermine and the age requirement is > 16 years old, and confirmed that the length of treatment is recommended to be few weeks. 	
3. DUR Board Recommendations	 Dr. Burke recommends adding phentermine to the current PA for weight loss drugs which include Xenical® and Meridia®. With no further board discussion, a motion was place before the board. 	 Two motions were made: 1.Dr Grauer motioned to cancel the 1995 PA criteria and was seconded by Mr. Wilcox. 2. Dr. Kentfield motioned to redraft the weight loss PA criteria to include phentermine and present to the board at the next scheduled meeting for approval. The motion was seconded by Ms. Kroeger. Both motions carried unanimously by roll call.

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F. Medicare Part D-Overview	 Kay Wiese from the Division of Health Policy and Finance presented an overview on Medicare Part D. She reviewed how dual eligible/partial dual eligible beneficiaries would be affected by this change. In addition, the Senior Health Insurance Counseling for Kansas (SHICK) can answer questions for those eligible for the program. Mary presented financial data regarding Medicare Part D and the Kansas Medicaid Assistance Program 	Mary will send the phone number to Board members for Senior Health Insurance Counseling for Kansas(SHICK)
VI. Adjournment	There being no further discussion, a motion to adjourn was placed before the Board.	 A motion was made by Dr. Unruh and seconded by Dr. Grauer to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 11:45 a.m.